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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/857,869 | 06/12/2001 | Kazuhiko Take | 209334USOPCT | 1165 |

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EXAMINER

BERNHARDT, EMILY B

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1624

DATE MAILED: 03/13/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,869

Applicant(s)

TAKE et al.

Examiner

Emily Bernhardt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/20/02 and 1/15/03
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-18 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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In view of applicants' amendments and remarks the following applies.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The newly presented claim recites not only treating but also preventing a list of diseases which have not been all correlated to the activity relied on herein. Note Ohnmacht previously cited at best suggests treating asthma, emesis, pollakiuria and irritable bowel syndrome but not any and all types of mental diseases which the claim also recites. Treating anxiety disorders particularly described on p.23 of the specification would not be objected to in place of "mental diseases".

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11,13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyake (WO'954) for reasons of record. While newly presented claims have narrowed the choices at R4 to morpholino-containing groups, Miyake also teaches same type of substitution at piperazine terminus

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in otherwise similar compounds that only differ in not having a methyl in place of instant OH. See eg.80 (3) on p.158 of the WO publication.

While applicants have provided a complete certified copy of their foreign priority document to antedate Miyake, claims rejected herein are not entirely described in said priority paper. Note that the scope of substituents permitted in R1 and R2 herein are far broader than what is described in earlier application and last species of claim 13 not at all described. See In re Gostelli 10 USPQ 2d 1614 regarding requirements to entitlement to benefit under 35 USC 119. Claims 12 and 17-18 are entitled to benefit under 35 USC 119.

Claims 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuo for reasons of record. The Declaration filed under 37 CFR 1.132 by Dr. Matsuo has been considered but is not persuasive for the following reasons. The closest instant compound (i.e.having same R4 group) has NOT been tested alongside eg.81, which only differs in 1 respect from instant scope. Note that instant compound tested differs in 2 respects from eg.81. It may well be that activity is equally or more sensitive to changes at R4 than at R2 phenyl

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derivatives. Additionally, a difference of 5-fold activity has not been asserted by declarant as being an unexpected difference and of both statistical and practical significance as was emphasized in Ex parte Gelles 22 USPQ 2nd 1318. In applicants' specification testing was conducted to determine 80% inhibition not 50% inhibition as was done in the Declaration and there may be as much variability for instant compounds tested but not reported than what has been shown for prior art compound.

Claims 11-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6087357. There still remains overlapping subject matter with the claims of US'357, which corresponds to Matsuo maintained above, for which a patentable difference has not been demonstrated.

PTO records indicate that 09/899942 has gone abandoned with no refilings.

Claims 11-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/446145. Although the conflicting

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claims are not identical, they are not patentably distinct from each other because they still embrace overlapping subject matter as said application corresponds to WO'954 still applied above.

Evidence of common assignment between instant case and US'357 and serial no. 09/446145 is thus still needed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.



EMILY BERNHARDT

PRIMARY EXAMINER

GROUP 1600